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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,059

03/02/2004

Sang Yup Lee

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11/02/2005

INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
PO BOX 14329  
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

ROOKE, AGNES BEATA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/791,059

Applicant(s)

LEE ET AL.

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 6-15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-15, 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

This non-final action is in response to the Applicant's reply filed on 08/22/05

Claims 1, 3, 4, 6-15, and 18 are pending. Claims 2, 5, 16, and 17 have been cancelled.

The amendments to the claims filed on 08/22/2005 have been acknowledged.

The priority is claimed to REPUBLIC OF KOREA 10-2003-0062756, filed on 09/08/2003.

#### **Objections/Rejections Withdrawn**

The objection to the specification is withdrawn because the specification has been updated.

The rejection of Claims 16 and 17 under 35 U.S.C. 101 is moot, since the claims are cancelled.

The rejection of claims 1, 2, 3, 5, 8, and 17 under 35 U.S.C. 112, paragraph second are withdrawn because the names are spelled out and the reference in claims to tables is rectified.

The rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 16, and 17, under 35 U.S.C. 102(b) over Willsie et al. are withdrawn because Willsie et al. do not teach small heat shock proteins that are disclosed in the currently amended claims.

**Rejections Maintained**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 7 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the previous office action, examiner rejected claim 7 and stated that it must be specified or defined what the "protein mixture, " is for example combination of different proteins, or different proteins with other chemicals, or a single protein with other chemicals.

The Applicant amended the claim by inserting the phrase "combination of different proteins," however, it is still not clear what proteins are involved in the combination (what kind of proteins, and how many of them are present in the mixture).

Further, examiner also rejected claim 7, on the basis that it stated that claim 7 refers to "increased number of spots" on the gel, and that it is not clear what is the numerical value of the increase (for example, two-fold or 50%), thus the values for the increase in number of spots on the gel should be provided. But, the Applicant did not rectify this deficiency in the claim and the claim stands rejected, because the phrase stating "increased number of spots as compared to a gel obtained for a corresponding mixture lacking said at least one small heat

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shock protein” is indefinite, because it does not specifically points out how many spots are actually present and what is the numerical value of the “increase.”

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kitagawa et al., *Escherichia coli* Small Heat Shock Proteins, IbpA and IbpB, Protect Enzymes from Inactivation by Heat and Oxidants, *Eur. J. Biochem.*, (2002), 269, p. 2907-2917.

Kitagawa et al. teach two small heat shock proteins of *E. coli*, IbpA and IbpB. See page 2909, right paragraph (*Expression and purification of His-IbpA and His-IbpB* section).

The Applicant argues that Kitagawa et al. teach heat shock fusion protein constructs His-IbpA and His-IbpB, and not isolated IbpA or IbpB.

Examiner respectfully disagrees and states that claims as presented do not require that HSPs do not have labels or other purification moieties attached to them. Moreover, there is no basis in the specification for excluding these labels or purification moieties from HSPs either.

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In the specification paragraph [0047] the Applicant discusses preparation of IbpA-6-his and IbpB-6-his, for example; and in paragraph [0055] the purification of IbpA and IbpB is discussed, however, there is not mention whether 6-his tags are removed from IbpA or IbpB. Further, because it is not disclosed in the specification whether "6-his" tags are removed, examiner concludes that IbpA is equivalent to IbpA-6-his and IbpB is equivalent to IbpB-6-his. Therefore, the rejection stands.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Lubman et al. (U.S. 2002/0098595 A1).

Lubman et al. teach that heat shock proteins have been identified from the 2-D gel, See [0137] page 15; and provide a method analogous to the 2-D gel, where the method can be used for proteome analysis. See [0151] page 17.

Therefore, it would have been obvious to a person skilled in the art to design a method for the analysis of proteomes using 2-D gel electrophoresis where the method is analogous to the 2-D gel and uses heat shock proteins as disclosed by Lubman et al.

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The applicant argued that there is no teaching or suggestion in Lubman of applicants' claim 15 recited method of "using the composition of claim 1" in "the analysis of proteomes by 2-D gel electrophoresis," with the composition of claim 1; where Lubman by contrast only discloses that HS27 and that the use of such composition in performing proteomic analysis.

Examiner respectfully disagrees, because even though the exact heat shock proteins claimed in the instant invention are not pointed out in Lubman, there is a heat shock protein HS27 that is used in Lubman's analysis of proteomes using 2-D gel electrophoresis.

Claims 7, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willsie et al. in view of Kitagawa et al., Escherichia coli Small Heat Shock Proteins, IbpA and IbpB, Protect Enzymes From Inactivation by Heat and Oxidants, Eur. J. Biochem. (2002), 269, p. 2907-2917.

Willsie et al. teaches  $\alpha$ -crystallin protein p26 HSP bound to nuclear matrix proteins derived from embryos that were subject to 2-D gel electrophoresis, see page 606, right column and page 607, right column. Therefore, Willsie et al. teach compositions of small heat shock proteins including  $\alpha$ -crystallin protein p26 from Table 1. Willsie et al. teach a method of 2-D gel electrophoresis comprising adding small HSPs to a nuclear matrix protein mixture and subjecting the mixture to 2-D gel electrophoresis, wherein the sHSP is  $\alpha$ -crystallin p26 from Table 1. Claims 10 and 11 are included in this rejection because sHSPs were effective.

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Willsie et al. teach method of using sHSPs as inhibitors of protein degradation because in control blots the proteins were degraded. See Figure 2, page 606, and Figure 3, page 607. Willsie et al. does not teach the method for the gel electrophoresis wherein the protein mixture is total protein of specific cells of prokaryotes and eukaryotes, such as *E. coli* and *Pseudomonas*.

Kitagawa et al. teach two small heat shock proteins of *E. coli*, IbpA and IbpB. See page 2909, right paragraph (*Expression and purification of His-IbpA and His-IbpB* section). Kitagawa et al. teach two small heat shock proteins of *E. coli*, IbpA and IbpB, but do not teach 2-D gel electrophoresis.

It would have been obvious to a person skilled in the art to design a method for the 2-D gel electrophoresis as disclosed by Willsie et al. and use a protein mixture of IbpA or IbpB (sHSPs) from *E. coli* as disclosed by Kitagawa et al. because small heat shock proteins help to stabilize other proteins and remain associated with unfolded proteins in 2-D gel electrophoresis.

The Applicant argues that there is no motivation for the applicant's claimed invention of independent claim 7, since heat shock proteins of Kitagawa are heat shock proteins constructs including polyhistidine tags, and that there is no objective teaching or basis in either of the references for the proposed hypothetical combination of Willsie and Kitagawa.

Examiner respectfully disagrees because the constructs of heat shock proteins with the polyhistidine tags can be still used for 2-D gel electrophoresis purposes. Therefore the rejection stands.



**New Rejections**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3, 4, 6-11, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 4, the Applicant refers to "an effective amount" of small heat shock protein, however the effective amount is not specified in the claims or in the specification. Therefore, a numerical value or a range of values should be specifically provided in the claims.

In claims 1, 3, 6, 7, 8, 9, 10, 11, and 18, the Applicant refers to "at least one small protein" and the maximum possible amount of proteins is not provided or particularly pointed out. Therefore, the clarification as to the number of proteins should be provided.

***Conclusion***

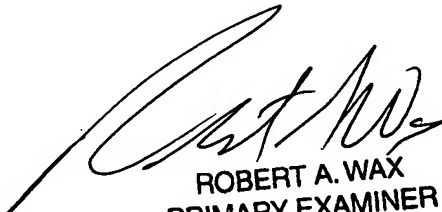
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax

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phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR



ROBERT A. WAX  
PRIMARY EXAMINER